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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,050	03/22/2004	James E. Kipp	IFT-6019	1570
7590 05/17/2007 MICHAEL MAYO, ESQ. BAXTER INTERNATIONAL INC. LAW DEPARTMENT ONE BAXTER PARKWAY, DF2-2E DEERFIELD, IL 60015			EXAMINER KUGEL, TIMOTHY J	
			ART UNIT 1712	PAPER NUMBER
			MAIL DATE 05/17/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/806,050	Applicant(s) KIPP ET AL.	
	Examiner Timothy J. Kugel	Art Unit 1712	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 March 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,5-7,9-14 and 16-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-7,9-14 and 16-28 is/are rejected.
- 7) ☒ Claim(s) 16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

1. Claims 1, 2, 5-7, 9-14 and 15-28 are pending as amended on 23 March 2007, claims 3, 4, 8 and 15 being cancelled.
2. The text of those sections of Title 35, US Code not included in this action can be found in a prior Office action.
3. Please note that due to a typographic error, claim 11, while treated in the rejection, was inadvertently left off the listing of claims rejected under 35 USC 102(b) as being anticipated by US Patent 5,314,506 (Midler hereinafter) in the previous Office action.

### ***Response to Amendment***

4. Applicant's cancellation of claims 3, 4 and 15, filed 23 March 2007, renders the following previously cited objections and rejections moot:

The objection to claim 3 because of informalities has been withdrawn.

The rejection of claims 3, 4, and 15 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn.

The rejection of claims 3, 4 and 15 are rejected under 35 USC 102(b) as being anticipated by US Patent 6,221,332 (Thumm hereinafter) has been withdrawn.

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The rejection of claims 3, 4 and 15 under 35 USC 102(b) as being anticipated by Midler has been withdrawn.

5. Applicant's amendment, filed 23 March 2007, with respect to the additional limitation of claims 1 wherein the nanoparticle suspension is prepared by dissolving an organic compound in a water miscible first solvent then solution is mixed with a second solvent to precipitate the organic compound and create a suspension of particles, has been fully considered and overcomes the following:

The rejection of claims 1, 2, 9, 10, 16 and 17 under 35 USC 102(b) as being anticipated by Thumm has been withdrawn.

6. Applicant's amendment, filed 23 March 2007, with respect to the additional limitation of independent claim 2 wherein at least one of the first or second streams contact an obstruction disposed between said first and second entrance points has been fully considered and overcomes the following:

The rejection of claims 2 and 16 and 17 under 35 USC 102(b) as being anticipated by Midler has been withdrawn.

### ***Claim Objections***

7. Claim 16 stands objected to because of the following informalities:

In claim 16 the word 'comprising' should appear between the phrase "the method of claim 2" and the word 'contacting'.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

8. Claims 1, 2, 5, 6, 9-14 and 16-19 stand and new claims 22-26 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2 and 5 each recite the limitation "mixing of at least some of the particles ~~in~~ from the first and second streams." It is unclear if this limitation means that the particles suspended in the first fluid stream are mixed into the second fluid stream or if particles from a second source—for which there would be insufficient antecedent basis—are mixed into the first and second fluid streams or if there are particles in both the first and second streams—for which there would be insufficient antecedent basis. For the purpose of examination, the claims were construed to recite, "...mixing of at least some of the particles from the first fluid stream into the second fluid stream."

Further, claim 1 recites the limitation "redirecting the fluid stream". There is insufficient antecedent basis for this limitation in the claim and it is unclear which fluid is being redirected. For the purpose of examination claim 1 was construed to recite, "redirecting the first fluid stream".

Claims 9-14 are dependent on claim 1, claims 16, 17 and 22-25 are dependent on claim 2 and claims 6, 18, 19 and 26 are dependent on claim 5.

***Claim Rejections - 35 USC § 102***

9. Claims 1, 5, 7, 9-11, and 18-20 stand and new claims 21, 27 and 28 are rejected under 35 USC 102(b) as being anticipated by Midler.

Midler teaches a method of producing a particle suspension comprising impinging jets of a solution of an organic compound in an organic solvent and an anti-solvent—including water—such that a high purity stable dispersion results (Column 2 Lines 16-19, Column 4 Line 55 – Column 5 Line 19 and Figures 2 and 3). Midler also teaches that the fluids of the process can contain a surfactant (Column 5 Lines 32-45) and that the fluids can be cooled with an ice bath (Example 2 Column 8 Line 55 – Column 9 Line 16). Midler shows that the fluid streams would impact on the flat and/or semi-spherical surfaces on both sides of the chamber and be re-directed in the substantially opposite direction as they enter the chamber (Figures 2 and 3). Further, Midler shows that the streams do not need to be directly impinging (Figure 2).

***Claim Rejections - 35 USC § 103***

10. Claim 6 stands rejected under 35 USC § 103(a) as being unpatentable over Midler as applied to claims 1, 5, 7, 9-11, 18-21 and 26-28 above in view of US Patent 3,685,261 (McIlvaine).

As detailed above, Midler teaches a method of producing a particle suspension comprising impinging jets of a solution of an organic compound in an organic solvent and an anti-solvent—including water—such that a high purity stable dispersion results. Midler also teaches that the fluids of the process can contain a surfactant and that the

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fluids can be cooled with an ice bath. Midler shows that the fluid streams would impact on the flat and/or semi-spherical surfaces on both sides of the chamber and be re-directed in the substantially opposite direction as they enter the chamber. Further, Midler shows that the streams do not need to be directly impinging.

Midler does not disclose expressly the use of the Venturi effect to combine the two fluid streams.

McIlvaine discloses a method and apparatus for dispersing two fluids including a Venturi (Column 1 Line 56 – Column 2 Line 15 and Figures 1-6).

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use the Venturi of the apparatus of McIlvaine in the method of Midler. The motivation to do so would have been to thoroughly mix and disperse the two fluids (McIlvaine Column 2 Lines 13-15).

### ***Response to Arguments***

11. Applicant's arguments filed 23 March 2007 have been fully considered but they are not persuasive.

Applicant argues that claim 16 has been amended to correct the objected to minor informality cited in the previous Office action; however, claim 16 shows no amendment.

Applicant further argues that claims 1, 2 and 5 have been amended to overcome the rejections under 35 USC 112, second paragraph, cited in the previous Office action; however, as shown above, these claims and their dependents are still indefinite.

Applicant argues that in independent claim 1, the steps wherein the nanoparticle suspension is prepared by dissolving an organic compound in a water miscible first solvent then solution is mixed with a second solvent to precipitate the organic compound and create a suspension of particles take place outside of the comminuting apparatus distinguish the claim from the teachings of Midler; however, the limitation "introducing said suspension into **a chamber** of a comminuting apparatus" (emphasis added) does not limit the steps preparing the suspension to take place outside the apparatus and the teachings of Midler read on the amended claim.

Applicant finally argues that in independent claims 5 and 7, that the limitation "substantially avoid direct impingement" distinguishes the claims from Midler; however, Midler's Fig. 2 shows that the streams may enter the chamber at angles less than 180° which therefore do not directly impinge each other.

#### ***Allowable Subject Matter***

12. Claim 2 would be allowable if rewritten or amended to overcome the rejection under 35 USC 112, 2nd paragraph, set forth in this Office action.

Claims 12-14, 16, 17 and 22-26 would be allowable if rewritten to overcome the rejections under 35 USC 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: Midler and McIlvaine, the closest prior art, fail to teach or fairly suggest cooling



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the second stream by mixing with a liquid or contacting the streams with an obstruction disposed between the entrance points of the first and second fluid streams.

### ***Conclusion***

13. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy J. Kugel whose telephone number is (571) 272-1460. The examiner can normally be reached 6:00 AM – 4:30 PM Monday-Thursday.

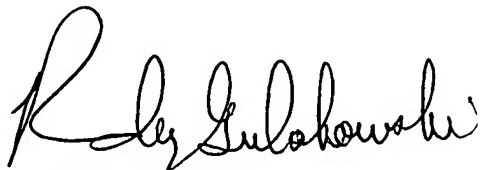
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on (571) 272-1302. The fax phone

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number for the organization where this application or proceeding is assigned is (571) 273-8300.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TJK  
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